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annular surface 44 which defines the chamfered perimeter edge 14 on anterior shell 12. A gate 46 is formed through upper die cover 34 and extends into the cavity formed between concave surface 38 and convex surface 42. The gate 46 is coupled to an injection molding system 48 suitable for injecting an elastomeric material into the cavity.

A second die assembly 50 is provided which includes the lower die cavity 32 used in the first die assembly 30 and a die plate 52. The die plate 52 has a generally flat upper die surface 54 which may abut the perimeter edge 14 of the anterior shell 12 and extends inwardly towards the nipple/areola region 20. As shown in FIG. 2B, the die cavity 32 is positionable into an abutting relationship with die plate 52 on a margin 56 which may be slightly relieved from the upper die surface 54. Gates 58 are formed in the margin 56 of the die plate 52 and extend from the horizontal surface to the boundary 60 of the die plate 52 for directing excess elastomeric material away from the prosthesis 10 during fabrication.

With reference now to FIG. 4, the fabrication process will be further explained. As presently preferred, a first mold cavity 32 is provided in an upright position with the concaved cavity facing upwardly. The nipple/areola region 20 of the breast prosthesis 10 is formed by depositing elastomeric material colored with pigments of red, purple and gold and mixed with rayon flocking fibers to simulate the color and texture of the nipple/areola region of a human breast. This material is permitted to partially cure.

While the nipple/areola region cures, the first mold cavity 32 is enclosed with a die cover 34 yielding a thin-walled cavity to define what will become the anterior shell 12. Conventional injection molding process is used to inject elastomeric material into the first mold assembly 30 and form the anterior shell 12. The anterior shell 12 is allowed to substantially cure, typically for approximately four hours.

Once the anterior shell 12 is cured, the die cover 34 is removed from the die cavity 32 and the sprue 48 extending from the interior surface of anterior shell 12 is trimmed. A die plate 52 is provided with the upper surface 54 which is spread with a partially cured elastomeric material. In this regard, it is important that the elastomeric material be partially cured to a degree sufficient such that its viscosity will allow the elastomeric material to remain on the relatively flat horizontal surface 54 formed on die plate 52. Alternatively, the die plate 52 may be provided with a seal or similar feature around the boundary 60 for confining the elastomeric material on the upper surface 54.

A layer of adhesive 62 is applied to the perimeter edge 14 of the anterior shell 12. A suitable adhesive is selected to enhance adhesion and induce vulcanization or similar process in which the polymer molecules are linked to other polymer molecules by atomic bridges to form an air tight bond. While a vulcanization process in presently preferred, other acceptable processes such as similar thermostatic or thermoplastic processes may be utilized to achieve an air tight interface.

Next, the die cavity 32 is rotated 180° from its position as shown in FIG. 1 into an inverted position as shown in FIGS. 2A and 2B. The die cavity 32 is then lowered on top of die plate 52 and aligned with pins 36 in a manner similar to that described with reference to FIG. 1. Sufficient adhesion exists between the anterior shell 12 and die cavity 32 to support the anterior shell 12 in the concave position above posterior portion 16. The interior cavity 18 defined by anterior shell 12 and posterior portion 16 captures ambient air to create air-filled interior cavity 18. The breast prosthesis 10 is allowed to fully cure, taking approximately three to six hours.

Once fully cured, the die plate 52 is removed from the die cavity 32. The breast prosthesis 10 is removed from die cavity

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32. The molded breast 10 may include some flash material extending from the perimeter regions which may be trimmed using conventional processes. The breast prosthesis 10 is then washed and talced to provide an acceptable tactile characteristic simulating that of the human skin.

The foregoing description of the embodiments has been provided for purposes of illustration and description. It is not intended to be exhaustive or to limit the invention. Individual elements or features of a particular embodiment are generally not limited to that particular embodiment, but, where applicable, are interchangeable and can be used in a selected embodiment, even if not specifically shown or described. The same may also be varied in many ways. Such variations are not to be regarded as a departure from the invention, and all such modifications are intended to be included within the scope of the invention.

What is claimed is:

1. An external breast prosthesis comprising:

a posterior shell; and

an anterior shell defining a cup shaped body having a uniform wall thickness and a chamfered perimeter edge, the posterior shell covering the cup-shaped body to form an air-filled interior cavity;

wherein the chamfered perimeter edge forms a mitered joint between the anterior shell and the posterior shell.

2. The external breast prosthesis of claim 1 wherein the anterior shell and the posterior shell are formed with an elastomeric material.

3. The external breast prosthesis of claim 2 comprising further comprising an adhesive layer interposed between the chamfered perimeter edge and the posterior shell.

4. The external breast prosthesis of claim 1 comprising further comprising an areola region formed on a surface of the anterior shell opposite the posterior shell.

5. The external breast prosthesis of claim 4 wherein the areola region has a nipple formed therein.

6. The external breast prosthesis of claim 4 wherein the anterior shell, the areola region and the posterior shell are formed with an elastomeric material, the areola region further including a flocking fiber.

7. An external breast prosthesis comprising an elastomeric anterior shell defining a cup shaped body having a uniform wall thickness, an elastomeric posterior shell covering the cup-shaped body and forming an air-tight interior cavity, and an air-filled chamber consisting of an air volume sealed within the interior cavity, wherein the anterior shell, the posterior shell and the air-filled chamber define a valve-less prosthesis.

8. The external breast prosthesis of claim 7 wherein the anterior shell has a chamfered perimeter edge forming a mitered joint with the posterior shell.

9. The external breast prosthesis of claim 8 comprising further comprising an adhesive layer interposed between the chamfered perimeter edge and the posterior shell.

10. The external breast prosthesis of claim 7 comprising further comprising an areola region formed on a surface of the anterior shell opposite the posterior shell.

11. The external breast prosthesis of claim 10 wherein the areola region has a nipple formed therein.

12. The external breast prosthesis of claim 9 the areola region further including a flocking fiber.

13. The external breast prosthesis of claim 1 consisting of the anterior shell, the posterior shell, and the air-filled interior cavity.